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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,292	04/10/2001	Alexey Ryazanov	601-1-098CIP	8327

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/17/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,292

Applicant(s)

RYAZANOV, ALEXEY

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 14-17, drawn to an isolated nucleic acid encoding a mammalian melanoma kinase, a vector and host cell comprising said nucleic acid, classified in class 435, subclass 252.1.
- II. Claims 4-6, 14-17, drawn to an isolated nucleic acid encoding a mammalian heart alpha kinase, a vector and host cell comprising said nucleic acid, classified in class 435, subclass 252.1.
- III. Claims 7-9, 14-17, drawn to an isolated nucleic acid encoding a mammalian kidney alpha kinase, a vector and host cell comprising said nucleic acid, classified in class 435, subclass 252.1.
- IV. Claims 10-11, 14-17, drawn to an isolated nucleic acid encoding a mammalian skeletal muscle alpha kinase, a vector and host cell comprising said nucleic acid, classified in class 435, subclass 252.1.
- V. Claims 12-13, 14-17, drawn to an isolated nucleic acid encoding a mammalian lymphocyte alpha kinase, a vector and host cell comprising said nucleic acid, classified in class 435, subclass 252.1.
- VI. Claims 18-20 and 29, drawn to an isolated melanoma alpha kinase protein and a pharmaceutical composition comprising said alpha kinase, classified in class 435, subclass 194.

- VII. Claims 18, 21-22 and 29, drawn to an isolated kidney alpha kinase protein and a pharmaceutical composition comprising said alpha kinase, classified in class 435, subclass 194.
- VIII. Claims 18, 23-24 and 29, drawn to an isolated heart alpha kinase protein and a pharmaceutical composition comprising said alpha kinase, classified in class 435, subclass 194.
- IX. Claims 18, 25-26 and 29, drawn to an isolated skeletal muscle alpha kinase protein and a pharmaceutical composition comprising said alpha kinase, classified in class 435, subclass 194.
- X. Claims 18, 27-28 and 29, drawn to an isolated lymphocyte alpha kinase protein and a pharmaceutical composition comprising said alpha kinase, classified in class 435, subclass 194.
- XI. Claims 30-35, drawn to an isolated antibody against an alpha kinase protein and a cell that produces said antibody, classified in class 530, subclass 387.1.
- XII. Claims 36-37, drawn to a method for treating an animal in need of increased activity of melanoma alpha kinase, classified in class 424, subclass 94.5.
- XIII. Claims 38-39, drawn to a method for treating an animal in need of increased activity of kidney alpha kinase, classified in class 435, subclass 94.5.

- XIV. Claims 40-41, drawn to a method for treating an animal in need of increased activity of heart alpha kinase, classified in class 435, subclass 94.5.
- XV. Claims 42-43, drawn to a method for treating an animal in need of increased activity of skeletal muscle alpha kinase, classified in class 435, subclass 94.5.
- XVI. Claims 44-45, drawn to a method for treating an animal in need of increased activity of lymphocyte alpha kinase, classified in class 435, subclass 94.5.
- XVII. Claims 46-47, drawn to a method for detecting the presence or activity of an alpha kinase protein, classified in class 435, subclass 7.1.
- XVIII. Claim 48, drawn to a method of testing the ability of a drug to modulate the kinase activity of an alpha kinase protein, classified in class 435, subclass 15.

For each of inventions I-III, VI-VIII, XI and XII- XVIII above, restriction to either the nucleic acid (Groups I-III), protein (Groups VI-VIII), antibody (Group XI) or methods of use/detection (Groups XII-XVIII), corresponding to *Homo sapiens* or *Mus musculus* is also required under 35 USC 121. Those SEQ ID NOs: which correspond to *Homo sapiens* are SEQ ID NOs: 26, 34, 30, and those which correspond to *Mus musculus* are SEQ ID NOs: 28, 36, 32. Further, for inventions XI and XVII- XVIII above, restriction is also required under 35 USC 121 to either melanoma alpha kinase, kidney alpha kinase,

heart alpha kinase, skeletal muscle alpha kinase, or lymphocyte alpha kinase. It is acknowledged that many of the claims which have been grouped into the above Groups read on only a single species within the Group as discussed above. These claims will be examined to the extent that they read on the above elected Group.

Applicants should note that Claims 14-18 and 29 are included within more than one group. If applicants elect any of Groups I-V, Claims 14-17 will be examined only to the extent they recite the subject matter of the elected group. Similarly if applicants elect any of Groups VI-X, claims 18 and 29 will be examined only to the extent they recite the subject matter of the elected group.

The inventions are distinct, each from the other because of the following reasons:

Inventions corresponding to each of the nucleic acids (Groups I-III), proteins (Groups VI-VIII), antibodies (Group XI) or methods of detection (Groups XVII-XVIII), corresponding to *Homo sapiens* or *Mus musculus* alpha kinases, corresponding to each of the alpha kinases selected from the group consisting of: melanoma alpha kinase, kidney alpha kinase, heart alpha kinase, skeletal muscle alpha kinase, or lymphocyte alpha kinase are structurally unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, correspond to structurally different polypeptides

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and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions I-XI are structurally unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the DNA of Groups I-V, the proteins of Groups VI-X, and the antibodies of Group XI, each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNAs of Groups I-V comprise a nucleic acid sequence and the proteins of Groups VI-X and each comprise an unrelated amino acid sequence. The DNA has other utility besides encoding the proteins of Groups VI-X such as a hybridization probe and the proteins can be made by another method such as isolation from natural sources or chemical synthesis.

Inventions VI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the alpha kinase proteins of Group VI can be used to induce the antibodies of Group XI.

The DNAs of Groups I-V, the alpha kinase proteins of Groups VII-X and the antibodies of Group XI are distinct from the method of Group XII, as these products are neither made nor used by the method of Group XII.

Inventions VII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP, 806.05(h)). In the instant case the alpha kinase proteins of Group VII can be used to induce the antibodies of Group XI.

The DNAs of Groups I-V, the alpha kinase proteins of Groups VI and VIII-X and the antibodies of Group XI are distinct from the method of Group XIII, as these products are neither made nor used by the method of Group XIII.

Inventions VIII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP, 806.05(h)). In the instant case the alpha kinase proteins of Group VIII can be used to induce the antibodies of Group XI.

The DNAs of Groups I-V, the alpha kinase proteins of Groups VI-VII and IX-X and the antibodies of Group XI are distinct from the method of Group XIV, as these products are neither made nor used by the method of Group XIV.

Inventions IX and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP, 806.05(h)). In the instant case the alpha kinase proteins of Group VIII can be used to induce the antibodies of Group XI.

The DNAs of Groups I-V, the alpha kinase proteins of Groups VI-VII and IX-X and the antibodies of Group XI are distinct from the method of Group XV, as these products are neither made nor used by the method of Group XV.

Inventions X and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP, 806.05(h)). In the instant case the alpha kinase proteins of Group VIII can be used to induce the antibodies of Group XI.

The DNAs of Groups I-V, the alpha kinase proteins of Groups VI-IX and the antibodies of Group XI are distinct from the method of Group XVI, as these products are neither made nor used by the method of Group XVI.

Inventions VI-X and XVII-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP, 806.05(h)). In the instant case the alpha kinase proteins of Groups VI-X can be used to induce the antibodies of Group XI.

The DNAs of Groups I-V and the antibodies of Group XI are distinct from the methods of Groups XVII-XVIII, as these products are neither made nor used by the methods of Groups XVII-XVIII.

The methods of Groups XII-XVIII are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a stylized flourish extending from the end.

Richard Hutson, Ph.D.
Patent Examiner
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December, 16, 2002